

***Remarks***

The Office Action mailed July 25, 2003 (Paper No. 15) has been carefully reviewed and the following is made in response thereto. Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

The amendments to the specification are made solely to update the status of U.S. application 08/320,982, which is now U.S. Patent No. 5,801,026.

Applicants respectfully assert that the foregoing amendments introduce no prohibited new matter into the specification.

***Status of the Claims and Response to Restriction Requirement***

Claim 38 has been withdrawn by the Examiner as being drawn to an allegedly non-elected invention. Applicants note that the Office Action Summary at box no. 6 indicates that "Claim(s) 13, 26, 27, 31 and 35-41 is/are rejected." This statement is incorrect in that claim 38 was withdrawn from consideration and should not have been included in the rejection. Furthermore, claim 13 was canceled in the Amendment and Response to the Restriction Requirement filed on May 12, 2003 and was not before the Examiner at the time the Office Action was mailed.

Claims 26, 27, 31 and 35-41 have been newly canceled without prejudice or disclaimer. Thus, as a result of this amendment, newly added claims 42-46 are now pending.

The Office Action acknowledges Applicants' election of Group IV but states that "[b]ecause Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse." Office Action at page 2. Applicants do not understand the Examiner's statements considering that the Response to the Restriction Requirement filed May 12, 2003 was with traverse and was accompanied by two and one-half pages of detailed comments specifically pointing out the errors in the restriction requirement. As discussed therein, the pending claims had been rewritten so that they recite a specific unifying characteristic common to all of the claimed oils regardless of their source. This characteristics is that

the hydroxylated fatty acid content of the oil is increased compared to the hydroxylated fatty acid content of oil obtained from seeds of the same plant species without the recombinant DNA construct. Applicants respectfully request, again, that the restriction requirement be reconsidered and that the newly presented claims be considered.

***Indication that the Claims are Free of the Prior Art***

Applicants acknowledge, with appreciation, the indication made in the Office Action at page 8 that the claims are free of the prior art.

***Objection to the Specification***

The specification has been amended to update the status of U.S. application 08/320,982, now U.S. Patent No. 5,801,026 as requested in the Office Action at paragraph no. 2, page 2. Withdrawal of the objection is requested.

***Objection to the Claims***

Claim 36 is objected to because it is alleged to recite non-elected plant species. As stated above under "Status of the Claims and Response to Restriction Requirement," Applicants have not received from the Office a response to the detailed comments filed in reply to the Restriction Requirement by Applicants on May 12, 2003. However, the issue is now moot given that Applicants have newly canceled claim 36. The Examiner is respectfully requested to withdraw the objection in view of the cancellation of claim 36.

***The Rejection of Claims under 35 U.S.C. § 112, Second Paragraph***

Claims 26, 27, 31, 35-37 and 39-41 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse the rejection as it applies to newly presented claims 42-46.

Claims 26 and 27, and claims dependent thereon, are alleged to be indefinite because "the seeds having increased hydroxylated fatty acid content could not be from the same plant, but could be from a plant of the same species" (Office Action, page 3,

paragraph 5). Claims 26 and 27 have been newly canceled without prejudice or disclaimer. Without acquiescing to the grounds of the rejection and solely in an effort to expedite prosecution, Applicants' newly presented claims require that the modified and unmodified plants referenced in the claims be from the same plant species. Withdrawal of the rejection is requested.

Claim 36 is alleged to be indefinite because it is asserted that it is allegedly not clear what is intended by the term "Canola." The Office Action suggests that Applicants "amend the claims to recite "*Brassica napus*", instead of "Canola" and that "rapeseed" also be deleted from the claim" (paragraph no. 5, page 3). Without acquiescing to the grounds of the rejection and solely in an effort to expedite prosecution, Applicants have submitted new dependent claims 45 and 46 that do not recite "Canola" or "rapeseed" and newly recite "*Brassica napus*" in place thereof. One of ordinary skill in the art recognizes that "*Brassica napus*" is the scientific name for the group of plants commonly referred to as canola, rape and/or oilseed rape. See, e.g., III. Crop Nomenclature: Scientific Names, In Glossary of Crop Science Terms, Robert F. Barnes and James B. Beard (eds.), page 73, Crop Science Society of America, July 1992 (copy attached for reference). Withdrawal of the rejection is requested.

Claim 39 is alleged to be indefinite because it does not further limit the claims from which it depends. Without acquiescing to the grounds of the rejection and solely in an effort to expedite prosecution, Applicants have newly canceled claim 39. Withdrawal of the rejection is requested.

***The Rejection of Claims under 35 U.S.C. § 112, First Paragraph***

Claims 26, 27, 31, 35-37 and 39-41 stand rejected under 35 U.S.C. § 112, first paragraph because they are alleged to lack written description support. Applicants respectfully traverse the rejection as far as it relates to newly pending claims 42-46.

The Office Action acknowledges that the specification describes transformed *Arabidopsis* plants having elevated levels of hydroxylated fatty acids compared to non-transformed plants but asserts that 1) there is allegedly no description provided regarding the level of hydroxylated fatty acid content in the non-transformed plant to which the

comparison is made; 2) the specification allegedly does not set forth what the level of each and every hydroxylated fatty acid would be from plant species that have not been transformed; 3) it is allegedly impossible to determine what the characteristics are of oil having an increased content of fatty acids; 4) the specification allegedly does not provide written description that would allow a person skilled in the art to distinguish oil that is claimed from oil that comprises at least one hydroxylated fatty acid; and 5) it is alleged that no transformed plants other than *Arabidopsis* have been described.

Applicants respectfully disagree with the basis of the rejection for the following reasons.

As a first point, Applicants point out that there is no requirement in U.S. patent law that every claimed embodiment to be present in the application as an Example. All that is required is that the application contain a "written description of the invention." 35 U.S.C. § 112, first paragraph. Applicants respectfully assert that the present claims fully meet this requirement because the characteristics of the claimed oil are described in sufficient detail such that a person having ordinary skill in the art would recognize that Applicants were in possession of the claimed invention at the time of filing.

The Office Action asserts in point 1) recited above, that there is allegedly no description provided regarding the level of hydroxylated fatty acid content in the non-transformed plant to which the comparison is made. Applicants respectfully disagree. All that is required is that the claimed oil have an increased hydroxylated fatty acid content compared to oil obtained from seeds of the same plant species without the recombinant DNA construct. It is irrelevant what the level is of the hydroxylated fatty acid content in the non-transformed plant because all that is required is that the claimed oil have an increased level. Determining if one oil has an increased level compared to another oil is a simple matter of making a direct comparison of the hydroxylated fatty acid content in each sample. Furthermore, Applicants have provided the fatty acid compositions of *Arabidopsis* seed lipids from the wild type and six transgenic lines. See, Table 2 on page 83 of the specification. The comparisons in this table clearly demonstrate a higher level of hydroxylated fatty acid in the lipids of the transformed plants versus the wild type plants.

The Office Action asserts in point 2 above, that the specification allegedly does not set forth what the level of each and every hydroxylated fatty acid would be from plant species that have not been transformed. Applicants respectfully disagree. Again, it is irrelevant what the level of each and every hydroxylated fatty acid would be from plant species that have not been transformed because all that is required is that the claimed oil have an increased level. Determining if one oil has an increased level compared to another oil is a simple matter of making a direct comparison of the hydroxylated fatty acid content in each sample. It is an easy matter to look at results such as those provided in Table 2 so as to see whether the hydroxylated fatty acid content has been increased in accordance with the methods of this invention. As demonstrated in Example 4 of the specification, transforming a plant with the construct set forth in claim 26 will result in the production of plants with increased levels of hydroxylated fatty acid content in the seed lipids obtained from the transformed plants as compared to the non-transformed plants of the same species.

The Office Action asserts in point 3 above, that it is allegedly impossible to determine what the characteristics are of oil having an increased content of fatty acids. Applicants respectfully disagree. The characteristic recited in the claims which is relevant to whether or not the oils have been sufficiently described is that the oil have an increased level of hydroxylated fatty acid content compared to oil obtained from seeds of the same plant species without the recombinant DNA construct. Other characteristics that the oils may or may not have are simply not relevant.

The Office Action asserts in point 4 above, that the specification allegedly does not provide written description that would allow a person skilled in the art to distinguish oil that is claimed from oil that comprises at least one hydroxylated fatty acid. Applicants respectfully disagree. All that is required is that the claimed oil have an increased hydroxylated fatty acid content compared to oil obtained from seeds of the same plant species without the recombinant DNA construct. Determining if one oil has an increased level compared to another oil is a simple matter of making a direct comparison of the hydroxylated fatty acid content in each sample.

The Office Action asserts in point 5 above, that no transformed plants other than *Arabidopsis* have been described. Applicants respectfully disagree. Applicants exemplify transformed *Arabidopsis* plants in Example 1, pages 49-61. Applicants also state on pages 60-61 that *Arabidopsis* is widely accepted by plant biologists as a model for higher plants and the exemplification in the application of transformed *Arabidopsis* is meant to demonstrate the general utility of the invention in higher plants. Included within these higher plants are closely related species such as the crop plants *Brassica napus*, *Brassica juncea* or *Crambe abyssinica*. As stated previously, there is no requirement in U.S. patent law for every embodiment of a claimed invention to be exemplified in a patent application. All that is required is that the application contain a "written description of the invention." 35 U.S.C. § 112, first paragraph.

The Examiner is respectfully requested to withdraw the written description rejection in view of the newly presented claims and for the reasons stated above.

Claims 26, 27, 31, 35-37 and 39-41 stand rejected under 35 U.S.C. § 112, first paragraph because while being enabled for oil obtained from *Arabidopsis* that has been transformed with a nucleic acid sequence encoding a fatty acid hydroxylase, which comprises ricinoleic, lesquerolic, densipolic, and auricolic acid, allegedly does not provide enablement for oil from a plant that has been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase, wherein said oil has a hydroxylated fatty acid content that is increased compared to the hydroxylated fatty acid content from an oil obtained from seeds of the same plant that has not been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase. Applicants respectfully traverse the rejection as far as it relates to newly pending claims 42-46.

Each of newly presented claims 42-46 require that the oil with the increased hydroxy fatty acid and/or ricinoleic acid content be obtained from a plant "which has been modified to include a nucleic acid sequence coding for a kappa hydroxylase". Applicants refer the Examiner to the discussion immediately above as support that the full scope of the pending claims is fully supported by the as-filed specification.

Applicants have demonstrated that they were able to obtain seed oil characterized by its hydroxy fatty acid content by transforming a model plant species (*i.e.*, *Arabidopsis*)

with a nucleic acid encoding a kappa hydroxylase. The plant species utilized by Applicants is universally recognized as a model system used to study plant genetics, wherein the results of such studies have wide-spread application to many, if not most, plant species in the world. For example, The Agbiotech Inforsource (Issue 40, (November 1998) copy attached) states the following:

“The *Arabidopsis* genes that guide the production of oils are closely related to those that produce oils in crops like soybeans and canola. The understanding of these genes has been used to identify corresponding genes in oilseed crops.”

As another example, Focks and Benning (Plant Physiol. 118:91-101 (1998), copy attached), in discussing their genetic research on oil deposition in developing seeds, state the following:

“Although canola seems to be more suitable for the physiological approach described above, its close relative *Arabidopsis* is the better genetic model organism.”

One of ordinary skill in the art recognizes that transforming other seed-bearing plant species as taught by Applicants' invention using *Arabidopsis* as a model will result in the production of seed oil with an altered hydroxy fatty acid content. For these reasons, the Examiner is respectfully requested to withdraw the rejection.

**CONCLUSION**


In view of the foregoing remarks, Applicants respectfully request withdrawal of all outstanding rejections and early notice of allowance to that effect. Should the Examiner believe that a telephonic interview would expedite prosecution and allowance of this application, she is encouraged to contact the undersigned at her convenience.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No.50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

**MORGAN, LEWIS & BOCKIUS LLP**

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Erich E. Veitenheimer  
Reg. No. 40,420

**Customer No. 009629**  
**MORGAN, LEWIS & BOCKIUS LLP**  
1111 Pennsylvania Ave., N.W.  
Washington, DC 20004  
202.739.3000 (voice)  
202.739.3001 (fax)